

Application No. 10/772,716  
Amendment dated March 22, 2007  
Reply to Official Action of January 11, 2007

**REMARKS**

Claims 1-43 are pending in this application. Claims 1-3, 5, 6, 8, 9, 25-27, 30 and 31 have been amended.

In the Notice of Non-Compliant Amendment, the Examiner has noted that the claims were truncated and claim 43 did not show up in the previous Amendment. The claims have now been amended to include the original claim 43. Applicant's appreciate Examiner's assistance with this matter.

To review the earlier response to the Restriction Requirement, the Examiner contends that the application contains distinct inventions and requires restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim(s) 1 in part, 2 in part, 4, 17-24 in part, drawn to a method of treating pulmonary disease by administration of a FoxA2 protein, classified in class 514, subclass 2.
- II. Claim(s) 1 in part, 2 in part, 5-16, 17-24 in part, drawn to a method of treating pulmonary disease by administration of a nucleic acid encoding a FoxA2 protein, classified in class 514, subclass 44.
- III. Claim(s), 1 in part, 2 in part, 3, 17-24 in part, drawn to a method of treating pulmonary disease by administration of a FoxA2 receptor-specific antibody protein classified in class 424, subclass 130.1.
- IV. Claim(s) 25 in part, 26 in part, drawn to method of prescribing treatment and a method of prophylactically treating airway hyperresponsiveness by administration of a FoxA2 protein, classified in class 514, subclass 2.
- V. Claim(s) 25 in part, 26 in part, to drawn to method of prescribing treatment and a method of prophylactically treating airway hyperresponsiveness by administration of a nucleic acid molecule encoding a FoxA2 protein, classified in class 514,

subclass 44.

- VI. Claim(s) 25 in part, 26 in part, drawn to method of prescribing treatment and a method of prophylactically treating airway hyperresponsiveness by administration of a receptor-specific antibody, classified in class 424, subclass 130.1.
- VII. Claim(s) 27-31, drawn to a method of improving gas exchange, classification dependent upon the recitation of the anti-inflammatory agent.
- VIII. Claim(s) 32-34 in part, 40, 41-43 in part, drawn to a formulation for protecting a mammal from airway hyperresponsiveness comprising an anti-inflammatory agent and a FoxA2 receptor-specific antibody, classified in class 530, subclass 387.1.
- IX. Claim(s) 32-34 in part, 35, 41-43 in part, drawn to a formulation for protecting a mammal from airway hyperresponsiveness comprising an anti-inflammatory agent and a FoxA2 protein, classified in class 530, subclass 350.
- X. Claim(s) 32-34 in part, 36-39, 41-43 in part, drawn to a formulation for protecting a mammal from airway hyperresponsiveness comprising an anti-inflammatory agent and a nucleic acid molecule encoding a FoxA2 protein, classified in class 536, subclass 23.5.

This restriction requirement is hereby respectfully *traversed*. This restriction requirement is improper for numerous reasons, as follows:

Applicants believe that, at a minimum, Examiner should rejoin groups I, II, IV, and V.

All of the claims in groups I, II, IV, and V of the present application involve the same basic ingredient. That is, the present claims all require treating pulmonary disease by administration of a FoxA2 protein. Groups I and II are identical except for the fact that Group II is a method of delivering the FoxA2 protein *in situ*. Both Groups I and II involve the delivery of the FoxA2 protein into the lung, Group II is subset of the genus in Group I where instead of delivering the protein as prepared outside the body and then delivered to the lung, the protein is created within the lung and delivered to the lung. In either case, the end result is the same.

Application No. 10/772,716  
Amendment dated March 22, 2007  
Reply to Official Action of January 11, 2007

In Groups IV and V, the methods are identical to Groups I and II except that the treatment prophylactically delivered to the airway. Therefore, all claims of Groups I, II, IV and V require the same polypeptide and methods and the restriction requirement should be removed for these groups.

In order to search any of the present claims, the Examiner will have to search the same FoxA2 protein treatment of an airway art. The art is a relatively small field, and considering all the claims together would not place a serious burden on the Examiner.

The MPEP § 803 II. guidelines state:

Where plural inventions are capable of being viewed as related in two ways, both applicable criteria for distinctness must be demonstrated to support a restriction requirement.

As the claims are related in two ways as discussed above, both applicable criteria for distinctness shown in MPEP § 803 I, must be demonstrated to support a restriction requirement. The two criteria of MPEP § 803 I, are that the inventions must be independent, and that there would be a serious burden on the Examiner if the restriction was not required. Both of these criteria have been rebutted.

Administering an expression vector encoding for the FoxA2 protein is merely another means of delivering (administering) the protein, not a wholly new invention. In these instances, the protein to be administered is produced *in situ* within the cell instead of being delivered pre-made into the cell

For these reasons, the restriction requirement defined by the Examiner is improper. Accordingly, it is respectfully requested that the restriction requirement be withdrawn and Groups I, II, IV, and V be rejoined encompassed by Claim(s) 1 in part, 2 in part, 3-24 claim 25 in part, and 26 in part.

If in the event the Examiner maintains the restriction requirement, the Applicant elects **Group 1** with traverse.

Application No. 10/772,716  
Amendment dated March 22, 2007  
Reply to Official Action of January 11, 2007

Furthermore, in order to be complete, the Applicants elect the following species for the pulmonary disease: (d) acute inflammatory lung disease. For the anti-inflammatory agent, Applicants choose (4) glucocorticosteroid.

Applicants understand that, upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicants' undersigned attorney has made a good faith effort to be responsive to the restriction requirement made in the Office Action dated October 11, 2006 and the Notice of Non-Compliant Amendment dated January 11, 2007. If the Examiner would like to discuss the restriction requirement or to have Applicants provide any clarification of its terms, he is invited to contact Applicants' undersigned attorney at the phone number given below.

The Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully submitted,

JEFFREY A. WHITSETT

By



---

Stephen R. Albainy-Jenei  
Registration No. 41,487  
Attorney for Applicant(s)  
FROST BROWN TODD LLC  
2200 PNC Center  
201 East Fifth Street  
Cincinnati, Ohio 45202  
(513) 651-6823  
[salbainyjenei@fbtlaw.com](mailto:salbainyjenei@fbtlaw.com)